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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/099,864

03/13/2002

John M. Barker

1032-P02467US1

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7590

04/21/2006

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EXAMINER

AHMED, AAMER S

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 04/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/099,864

Applicant(s)

BARKER ET AL.

Examiner

Aamer S. Ahmed

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,6-8,10-19,22-32 and 54-89 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,6-8,10-19,22-32 and 54-89 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Allowable Subject Matter

The indicated allowability of claims 1-19, 22-31 and 54-79 is withdrawn in view of the newly discovered reference(s) to Boitch et al U.S. Publication 2004/0111063 A1. Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4-10, 13-30, 32, 54-57, 60-73 and 76-79 rejected under 35 U.S.C. 102(e) as being anticipated by Boitch et al U.S. Publication 2004/0111063.

Boitch et al discloses a pre-filled retractable needle injection ampoule device comprising a hollow barrel (310); a vial holder (304) displaceable within the barrel having a socket (301) configured to receive the vial (320); a needle (316) having a sharpened tip operable between an exposed position in which the sharpened tip projects forwardly from the barrel (310) and a shielded position in which the sharpened tip is shielded from contact (see figures 5A-5C); and a transfer chamber (338) within the barrel (310), wherein the transfer chamber (338) is adapted to be in fluid communication with the needle (316); wherein after use the needle is disposed in the shielded position; and wherein the vial (320) contains a quantity of medicinal fluid, wherein the vial comprises a container having a fixed rearward wall (see figure 5A) and a fixed pierceable wall (301) sealing the forward end; a biasing element (340) biasing the needle toward the retracted position; a needle retainer (326) releasably retaining the needle in the extended position against the bias of the biasing element (340); a pressuring element (356), an activation surface

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cooperable with the needle assembly and adapted to activate automatic retraction of the needle after use (see figure 5C and paragraph 0008).

Furthermore, Boitch et al teaches that the device comprises a conduit (307); an air-pump chamber (318) disposed within the vial holder, a lock (305) releasably locking the vial holder (304) and the barrel (310), a piston (356) and wherein the transfer chamber (338) is displaceable relative to the needle (see figure 6B) and that the vial holder (304) is at least partially disposed within the barrel. Additionally, Boitch discloses that the device comprises a rear pierceable seal (301) and a forward pierceable seal (322), and wherein the chamber (338) is disposed in a first housing (304) and a second housing (328), wherein the first housing (304) is displaceable relative to the second housing (328), operating to expel the medicinal fluid from the chamber (338) through the injection needle (316); and wherein the device comprises a stop (302).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 11, 12, 31, 58, 59, 74, 75 and 80-89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boitch et al in view of MacFarlane U.S. Patent Number 5,181,909. Boitch et al disclose the device as disclosed above, but fails to disclose a sliding valve element.

MacFarlane discloses a similar device with a sliding valve (combination of 17 and 18).

It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the device of Boitch et al by incorporating the sliding valve element of the type taught by MacFarlane, in order to control the injection pressure of the ampoule fluid.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 5658259 A Pearson; William R. et al.

US 4861335 A Reynolds; David L.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aamer S. Ahmed whose telephone number is 571-272-5965. The examiner can normally be reached on Monday thru Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



A. Ahmed



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